

PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Teumer et al.	Confirmation No.:	5032
Serial No.:	10/534,428	Art Unit:	1657
Filed:	May 10, 2005	Examiner:	Tiffany Maureen Gough
Customer No.:	21559		
Title:	CULTIVATION OF HAIR INDUCTIVE CELLS		

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Commissioner for Patents
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PETITION TO WITHDRAW FINALITY UNDER 37 C.F.R. § 1.181

Applicants respectfully request withdrawal of finality of the Office Action issued in connection with the above-referenced application on October 14, 2008.

REMARKS

Applicants respectfully request that finality of the present Office Action (mailed October 14, 2008) be withdrawn.

The facts of the case are as follows:

On March 5, 2008, after the filing of a Request for Continued Examination by Applicants on December 21, 2007, the Office issued a non-final Office Action that included a single rejection of claims 1, 7-21, and 29-33 under 35 U.S.C. § 103(a) for obviousness over WO 99/01034 in view of WO 00/69449, WO 01/74164, and Kishimoto (Genes and Development 14:1181-1185, 2000), as supported by Zhu et al. (Cancer Research 64:7918-7926, 2004). The Office stated:

WO '034 discloses a method for producing new hair growth comprising culturing human dermal papilla cells in a conditioned medium.

WO '449 disclose conditioned cell culture medium compositions and their methods of use. The medium may be conditioned with any eukaryotic cell type (p. 5, lines 30-34) including...[cells] of the genitourinary tract, i.e. encompassing the prostate (p. 12, lines 13-20).

Neither reference teaches cultivating hair inductive cells such as dermal papilla or sheath cells in conditioned medium conditioned with prostate epithelial cells. WO '164 teaches a method comprising culturing dermal papilla (DP) cells with cells expressing Wnt proteins to promote hair growth. The culturing of DP cells with Wnt maintains hair inductivity (p. 1, lines 17-19).

Kishimoto et al...teach Wnt signaling effects on DP cells when the cells were exposed to cells wexpressing Wnts 3a,4,5a, 7a.

Zhu et al demonstrate that prostate epithelial cells do express Wnt genes (abstract and Fig. 1A. Fig. 1A lane 1 clearly shows expression of most all genes in the Wnt family, including Wnt 4,5,7,11.

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to cultivate hair inductive cells such as dermal papilla (DP) cells in a conditioned medium as such methods are known in the art as taught by WO'034 and WO'449. Specifically it would have been obvious to

condition the medium with prostate epithelial cells because as taught by WO'164 and Kishimoto, Wnt signaling and co-culturing DP cells with cells expressing Wnt clearly maintains and promotes hair growth and inductivity. **While they do not teach prostate epithelial cells specifically, these cells are known...[to] express Wnt, as evidenced by Zhu who show expression of nearly all 19 Wnt genes.** (Office Action dated March 5, 2008, pp. 4-5; emphasis added.)

In a telephonic interview on June 5, 2008, and a reply filed on July 2, 2008, Applicants fully addressed the obviousness rejection, including remarks pointing out that none of the cited publications, namely WO 01/74164 and Kishimoto, teaches or suggests the use of prostate epithelial cells to condition media.

In the present Office Action dated October 14, 2008, the Office maintains the § 103 rejection of claims 1, 7-21, and 29-33 for obviousness over the same combination of publications, stating:

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to culture DP cells in a medium conditioned with prostate epithelial cells with a reasonable expectation for successfully cultivating hair inductive cells because it is known in the art that Wnt levels positively regulate the ability of dermal papilla cells to promote hair growth and culturing DP cells with Wnt expressing cells maintains hair inductivity. **Further, prostate epithelial cells are known to express genes as taught by WO'164 and Zhu.**

While WO'164 does not explicitly teach prostate epithelial cells, the rejection was constructed based on what was known in the art at the time of the invention, i.e., that prostate epithelial cells do express Wnt proteins... Therefore, given what was known in the art at the time of the claimed invention, the Office's conclusion is proper. (Office Action, pp. 5 and 8; emphasis added.)

The Office's basis for the present obviousness rejection is false. In addition, the Office designated the Office Action Final without fully addressing each of the points raised by Applicants. Thus, Applicants respectfully submit that finality was premature in this case.

The M.P.E.P. § 2141 states:

Office personnel fulfill the critical role of factfinder when resolving the *Graham* inquiries. It must be remembered that while the ultimate determination of obviousness is a legal conclusion, the underlying *Graham* inquiries are factual.

When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103. 35 U.S.C. 132 requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed. Clearly setting forth findings of fact and the rationale(s) to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability.

In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. (Emphasis added.)

Applicants believe that the Office has not given Applicant a “full and fair hearing...[so that] a clear issue between applicant and examiner...[can] be developed...before appeal” (M.P.E.P. § 706.07).

The Office erroneously rejects present claims 1, 7-21, and 29-33 by relying on teachings that are not present in WO 01/74164 and Kishimoto et al., and by relying on Zhu et al., which is not prior art to the present application. First, the Office states that “prostate epithelial cells are known to express Wnt genes as taught by WO’164” (Office Action, p. 5). The Office then repeatedly contradicts this statement by stating “While [WO 01/74164 and Kishimoto et al.] do not teach prostate epithelial cells specifically, these cells are known...[to] express Wnt, as evidenced by Zhu who show expression of nearly all 19 Wnt genes.” (Office Action, p. 4). It is improper for the Office to rely on WO 01/74164 and Kishimoto et al. to support the present

obviousness rejection of claims 1, 7-21, and 29-33, especially in light of the Office's own admission that these publications do not disclose the very subject matter for which the publications were cited. For this reason, the finality of the present Office Action should be withdrawn.

Second, the Office's reliance on Zhu et al. is improper. The present application claims benefit to the filing date of U.S. Serial No. 60/426,111, which is November 14, 2002. Zhu et al. was published more than one year after the '111 application was filed, i.e., on November 1, 2004. Thus, Zhu et al. is not prior art to the present application. Accordingly, the Office cannot rely on Zhu et al. to show "what was known in the art at the time of the invention, i.e., that prostate epithelial cells do express Wnt proteins" (Office Action, p. 8). Although the M.P.E.P. § 2143.03 states that "[r]eferences which do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the time the invention was made (*Ex parte Erlich*, 22 USPQ 1463 (Bd. Pat. App. & Inter. 1992))" (M.P.E.P. § 2143.03), in this case, the Office relies on Zhu et al. to show more than the level of ordinary skill in the art at or around the time the invention was made. Here, the Office relies on Zhu et al. for its disclosure that prostate epithelial cells express Wnt genes, a fact that was not known at the time Applicants' filed their priority application.

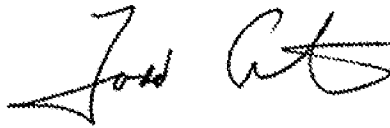
Furthermore, Zhu et al. is the only publication presently cited by the Office that even mentions prostate epithelial cells. Without Zhu et al., the present obviousness rejection would necessarily fail because none of the remaining publications, either singly or if combined, teaches or suggests a method for cultivating hair inductive cells, such as dermal papilla (DP) cells and dermal sheath (DS) cells, by culturing these cells in a culture medium that includes a medium conditioned by prostate epithelial cells, as is recited in present claims 1, 7-21, and 29-33. Thus,

the Office's reliance on Zhu et al. as showing "what was known in the art at the time of the invention" is improper. For this reason as well, the finality of the present Office Action should be withdrawn.

In order for Applicants to be given a full and fair hearing on the merits, Applicants respectfully request that finality of the present Office Action be withdrawn and that the issues discussed above be clearly addressed by the Office (see M.P.E.P. § 706.07(d): "If, on request by applicant for reconsideration, the primary examiner finds the final rejection to have been premature, he or she should withdraw the finality of the rejection").

If there are any charges or any credits, kindly apply them to Deposit Account No. 03-2095.

Respectfully submitted,



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Date: 15 December 2008

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